K123962

Sophono
bone conduction hearing solutions

APR 0 8 2013

510(k) Summary: Otomag Bone Conduction Hearing System

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, this summary of substantial equivalence information is being submitted.

Submitted By: Sophono, Inc.
5744 Central Avenue #100
Boulder, Colorado 80301

Establishment Registration Number: 3008514292

Contact Person:

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Date Prepared: March 4, 2013

Trade or Proprietary Name: Otomag Bone Conduction Hearing System

Regulation Number: 21 CFR §874.3300

Regulation Name: Hearing Aid, Bone Conduction

Regulatory Class: Class II

Product Code: LXB

Panel: Ear Nose and Throat Specialty Panel

Predicate Device: Otomag Bone Conduction Hearing System – K102199

Device Description:

The Otomag™ Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The subject of this 510(k) is to obtain a labeling claim relative to the use of MRI with the Alpha (M) Magnetic Implant to specify the implant as Magnetic Resonance (MR) Conditional.

The Otomag™ System is configured in either of two configurations. The first configuration is the Alpha (S), where the Otomag™ Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha (M), where the Otomag™ Sound Processor is attached magnetically to an implanted magnet. The Headband, Softband, or Magnetic Implant holds the sound processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag™ System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag™ System for individual patient hearing loss.

The system utilizes the same fundamental scientific principles, and has the same intended use and indications for use as the current legally marketed device, and represents that the magnetic implant can now undergo MRI scanning under certain conditions.

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Technological Characteristics:

The technological characteristics of the Otomag Bone Conduction Hearing System have not changed and are therefore equivalent to those of the predicate device.

Intended Use:

The Otomag Alpha Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up). This is the same intended use, and for the same patient population as the current legally marketed device.

MRI Information:

Voluntary Standards
Testing of the Alpha (M) Magnetic Implant for MRI compatibility conforms to all applicable requirements of the following National and International Standards:

ASTM F2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

ASTM F2052-06e1, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

ASTM F2213-06 (Reapproved 2011), Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.

ASTM F2182-11a, Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging.

ASTM F2119-07, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

MRI Scanning Conditions
Non-clinical testing demonstrated the Alpha (M) Magnetic Implant is MR Conditional and can only be scanned safely under the following conditions:

- remove all external components including the Otomag Alpha Sound Processor, Magnetic Spacer, Headband or Softband before entering the MR environment
- static magnetic field of 3 Tesla or less
- spatial gradient field of 720 Gauss/cm or less
- maximum whole-body averaged specific absorption rate (SAR) of 4 W/kg in the First Level Controlled Mode for a maximum scan time of 15 minutes of continuous scanning.

Magnetic Interactions
Testing for magnetic field interactions involved evaluations of translational attraction and torque for the Alpha (M) Magnetic Implant using a 3-Tesla MR system.

Translational Attraction
The maximum measured magnetic force using a digital force gauge was 2.29 Newtons (230-grams). This is within the range of forces expected in normal daily usage, where the external magnets may impose a force of up to 2.5 N on the implant.

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Torque
The qualitatively measured torque was +4 (very strong), showing a very rapid and very forceful alignment to the magnetic field.

The implant has a mass 3.6 grams. The translational attraction was 2.5 N (230 grams) and that the torque test consists of hanging the implant by a string in the magnetic field. Due to the very small mass of the implant and the relatively larger translational attraction, the implant aligned to the axis of the magnetic field.

In vivo, the implant was secured by 5 screws to the skull. Sophono validation testing measured a retention force of >31 N for each individual screw. The implant is secured to the skull with 5 screws which represents a holding force of over 150 N. In addition, during normal daily usage, the external magnetic spacer may impose a force up to 2.5 N on the implant.

Therefore, there are no concerns that the translational attraction or torque will cause a hazard to the patient.

MRI Related Heating
In non-clinical testing the Alpha (M) Magnetic Implant produced a maximum temperature rise less than 3.2°C during 15 minutes of continuous MR scanning in the First Level Controlled Mode at a maximum whole-body averaged SAR of 4 W/kg.

The computed implant temperature increase in response to the worst-case, time-averaged gradient field (94.7 Tesla/sec) for the 15 minute possible exposure for a series of clinical MRI scans is less than 2.6°C.

Image Artifact
The image artifact extends approximately 5 cm from the device when scanned in nonclinical testing using both T1-weighted, spin echo pulse sequence and Gradient echo (GRE) pulse sequence in a 3 Tesla/128-MH, Excite, Software 14X.M5, General Electric Healthcare, Milwaukee, WI; active-shielded, horizontal field MR system with a send receive RFcoil.

Implant Function Following MR Scanning
In non-clinical testing, when positioned parallel to the patient table, the Alpha (M) Magnetic Implant maintained over 95% of its original magnetic strength after 10 insertions into a static MRI field and over 10 minutes of pulse sequence in a 3 Tesla Siemens Tri Clinical MRI Scanner (MRC20587). To minimize demagnetization of the internal magnets, Sophono recommends that the patient's head is positioned along the long axis of the MRI scanner and that the patient is instructed to avoid head movement while lying on the patient table. If the head is tilted at an angle to the long axis of the patient table during a scan, the internal magnets may be demagnetized and a stronger external magnet may be needed to keep the device in place.

Conclusion:

Non-clinical testing of the Alpha (M) Magnetic Implant determined that a patient implanted with the implant can undergo MRI testing under certain conditions with no issues of safety or effectiveness raised. Based on the information provided, the labeling claim of Magnetic Resonance (MR) Conditional is proposed. The intended use, indications for use, and the fundamental scientific technological characteristics of the device have not changed. Based on the non-clinical performance testing, the Otomag Bone Conduction Hearing System is as safe and effective and considered to be substantially equivalent to the previously 510(k) cleared predicate device (K102199).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 8, 2013

Sophono, Inc.
% Ms. Krista B. Traynor, M.A., RAC
Director Regulatory Affairs
5744 Central Avenue #100
Boulder, CO 80301

Re: K123962
Trade/Device Name: Otomag Bone Conduction Hearing System
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid, Bone Conduction
Regulatory Class: Class II
Product Code: LXB
Dated: March 4, 2013
Received: March 7, 2013

Dear Ms. Traynor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic
and Ear, Nose, and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K123962

Device Name: Otomag Bone Conduction Hearing System

Indications for Use:

The Otomag™ Alpha Sound Processor is intended for use with the Otomag™ Headband or Otomag™ Softband (no age limitations), or with the Otomag™ Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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